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10/541,909

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Boris Y. Shekunov

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

11/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/541,909 | Applicant(s) SHEKUNOV ET AL. | |
| | Examiner Casey S. Hagopian | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 9/7/2010.

No claims have been amended. Claim 1-12 and 19 are cancelled. No claims have been newly added. Accordingly, claims 13-18 remain pending in the application and are currently under examination.

WITHDRAWN REJECTIONS

Applicant's arguments render the rejection(s) under 35 USC 102 and 103 moot over the Nielsen reference (USPN 5,716,558). Specifically, Nielsen teaches away from milling (see col. 1, lines 38-40). Thus, said rejections have been withdrawn.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW REJECTIONS

After further consideration, the following rejections have been newly added:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "the reducing step" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyagawa et al. (JP 07-196840, Abstract only) in view of Ravve et al. (USPN 3,323,946).

Miyagawa teaches producing polymeric particles by bringing a polymer into contact with carbon dioxide in a nearly supercritical or critical state in a pressurized extractor and then extruding the polymer melt through a die into a cooled solution between 0-90°C (abstract).

Miyagawa is silent to a milling step.

Ravve teaches reducing particle size of polymeric materials via milling in order to increase solubility (col. 8, lines 12-21). Ravve teaches particle sizes of about 12 microns (col. 8, lines 12-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include milling the polymer product of Miyagawa with a reasonable expectation of success because Ravve teaches an old and well known method of reducing particle size via milling in order to increase the solubility of said polymer.

Thus, the combined teachings of Miyagawa and Ravve render the instant claims obvious.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyagawa et al. (JP 07-196840, Abstract only) in view of Ravve et al. (USPN 3,323,946) and further in view of Barstow et al. (USPN 5,001,224).

Miyagawa and Ravve teach the elements discussed above.

Miyagawa and Ravve are silent to the particular polymers claimed in instant claim 16 including polypeptides.

Barstow teaches reacting supercritical carbon dioxide with polypeptides (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include other polymers such as polypeptides with a reasonable expectation of success because Barstow teaches such a method is effective and less expensive (col. 1, lines 11-17).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13 and 15-18 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-7 of U.S. Patent No. 6,986,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and instant application contain claims that are drawn to a method of producing particles comprising the steps of contacting a load material (e.g., a polymer and an active agent) with a supercritical fluid such as supercritical carbon dioxide to form a melt in a vessel/chamber and releasing or reducing the pressure of the vessel/chamber. It is noted that '846 discloses particular polymers including polysaccharides, polyesters, polyethers and so on (col. 5, lines 36-

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41). The claims of patent '846 do not include the step of milling, however it is well known that milling is useful in reducing particle size and patent '846 teaches that the resultant particles may be further milled to a desired particle size (col. 2, lines 41-45). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to further mill the obtained particles of the method advanced by '846 with a reasonable expectation of success because '846 teaches said milling can further reduce the particle size of said resultant particles and it is further well known that reduction in particle size is directly related to degradation and active agent release rates.

Thus, the subject matter of the claims of patent '846 render the instant claims obvious.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi, can be reached at 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Casey S Hagopian/
Examiner, Art Unit 1617

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1617